

### The Cited Art

**Shapland '306** shows (figures 8A, 8B) a drug delivery apparatus in which a balloon 84 is surrounded by a drug-containing polymer matrix 82.

"As used in conjunction with the present invention, the term "polymer matrix" includes synthetic polymers in the form of hydrogels or other porous or drug-permeable configurations or morphologies, such as polyvinyl alcohol, polyvinylpyrrolidone and polyacrylamide, polyethylene oxide, poly(2-hydroxy ethyl methacrylate); natural polymers such as gums and starches; synthetic elastomers such as silicone rubber, polyurethane rubber; and natural rubbers. The above examples are provided for reference only, and the range of suitable polymer matrix materials should not be construed as limited to those materials listed above." Column 9, lines 27-37.

"Drugs may be incorporated into the polymer matrix material by a variety of methods. The drug can be incorporated into the material as the polymer solution or dispersion is formed into the preferred annular shape; it can be added to the polymer matrix material after formation into the desired shape either passively or actively (through, for example, such methods as iontophoresis); the drug can be dissolved in a solvent (e.g., water, propylene, glycol, etc.) and the resulting solution can be incorporated into the polymer matrix material; or the drug molecules can be incorporated directly into the polymer matrix material." Column 9, lines 41-51.

Balloon 84 is expanded to press polymer matrix 82 against the vessel wall. Drugs may be delivered by iontophoresis using current supplied by wire 87 and electrode 86.

**Theron '005** shows a first occlusion catheter 4 including a tubular shaft 5 with a distal occlusion balloon 8 at its distal end.

"The distal occlusion balloon 8 is disposed at the distal end 7 of the first tubular shaft 5 and is positioned in its inflated condition distally of the area affected by plaque deposit 3. This is to establish a protective seal for particles detached from the vessel wall during the treatment." Column 4, lines 11-16.

A dilatation catheter 15 has a second tubular shaft 6 for coaxial reception of the first tubular shaft 5. A dilatation balloon 18 is mounted to the distal end of shaft 6 and is positioned at a stenotic target site with plaque deposit 3. Balloon 18 is expanded to open the vessel at the target site. Balloon 18 is then contracted and withdrawn. If they widened stenosis requires stenting, a stent delivery instrument 22, including a self-expanding stent 23 housed between shafts 24, 25, is extended over shaft 5 so to locate stent 23 at the stenosis. Outer shaft 25 is pulled to release self-expanding stent 23. Shafts 24, 25 are then withdrawn. If needed, a second dilatation catheter 15' may be used to place a balloon 18' within the expanded stent. Balloon 18' is then expanded to further anchor the implanted stent 23. The balloons 8 and 18 are collapsed and the apparatus removed leaving stent 23.

#### The Cited Art Distinguished

Independent **claims 26 and 30** have been rejected as anticipated by Shapland '306. Shapland '306 was described in the Office Action as including a porous tubular mesh (82). However, as discussed above, element 82 refers to a polymer matrix not a porous tubular mesh as presently claimed. Polymer material 82 is essentially a continuous, solid tube of material that can be expanded by balloon 84 so that the drug incorporated into the solid, polymer matrix material may be delivered to the surrounding tissue. Accordingly, Shapland '306 does not anticipate independent claims 26 and 30. It would not have been obvious to modify Shapland '306 to use a porous tubular mesh instead of the polymer matrix materials because (1) there is no suggestion to do so, and (2) doing so would change a fundamental aspect of the invention of Shapland '306, that is delivering a drug by expanding a continuous, solid tube of polymer matrix material.

Independent **claim 34** was rejected as anticipated by Theron '005. The Examiner states that Theron '005 discloses "then positioning at the target site an axially compressible, radially expandable tubular braid scaffolding mounted to the catheter shaft . . . ." Applicant disagrees. First, there is nothing in Theron '005 suggesting that stent 23 is an axially compressible, radially expandable tubular braid scaffolding. The stent 23 is stated to be a self-expanding stent, nothing more. Second, claim 34 recites that the balloon (corresponding to balloon 18 of Theron '005) is located at a first position along a catheter shaft (shaft 6 of Theron '005) and that the tubular braid scaffolding (corresponding generally to stent 23 of Theron '005) is mounted to the same catheter shaft at a second position along the catheter shaft. In contrast, stent 23 of Theron '005 is not

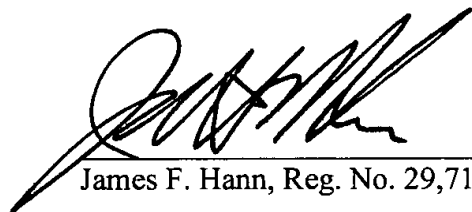
mounted to the same catheter shaft as is balloon 18; rather, stent 23 is housed between shafts 24, 25 of Theron '005. Therefore, claim 34 is not anticipated by Theron '005. It would not have been obvious to modify the structure of Theron '005 to arrive at the invention of claim 34 because (1) there is no suggestion in the art to do so, and (2) mounting stent 23 to shaft 6 would likely result in balloon 18 abutting against and potentially dislodging balloon 8 before stent 23 could be positioned adjacent to stenosis 3.

The **dependant claims** are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims. For example, **claim 28** recites the step of selecting an absorbent fiber tubular mesh and applying the agent to the absorbent fibers; Shapland '306 does not and does not suggest the use of use fibers for its drug delivery, but rather uses a polymer matrix. **Claim 31** recites that the positioning step is carried out using an axially-compressible and radially-expandable porous tubular braid as the porous tubular mesh; there is nothing in Wolff '535 which suggests replacing a fundamental element of Shapland '306, continuous polymer matrix 82, with a mesh material.

Applicant submits that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 3 March 2003



James F. Hann, Reg. No. 29,719

Haynes Beffel & Wolfeld LLP  
P.O. Box 366  
Half Moon Bay, CA 94019  
Ph. (650) 712-0340  
Fax (650) 712-0263  
jhann@hmbay.com